

DEPARTMENT OF THE AIR FORCE 59TH MEDICAL WING (AETC) JOINT BASE SAN ANTONIO - LACKLAND TEXAS

7 FEB 2016

MEMORANDUM FOR SGVU

ATTN: JOSHUA C. CALCOTE

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

- Your paper, entitled New FAQs Based on Resident Director's Feedback presented at/published to 59 MDW Clinical Research Division Knowledge Exchange Website & 59 MDW Email Bulletin in accordance with MDWI 41-108, has been approved and assigned local file #17064.
- 2. Pertinent biographic information (name of author(s), title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.
- 3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are 59 MDW staff member, we can forward your request for funds to the designated wing POC.
- 4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

hinda Steel-Goodwin

LINDA STEEL-GOODWIN, Col, USAF, BSC Director, Clinical Investigations & Research Support

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

INSTRUCTIONS

USE ONLY THE MOST CURRENT 59 MDW FORM 3039 LOCATED ON AF E-PUBLISHING

- 1. The author must complete page two of this form:
 - a. In Section 2, add the funding source for your study [e.g., 59 MDW CRD Graduate Health Sciences Education (GHSE) (SG5 O&M); SG5 R&D;
 Tri-Service Nursing Research Program (TSNRP); Defense Medical Research & Development Program (DMRDP); NIH; Congressionally Directed Medical Research Program (CDMRP); Grants; etc.]
 - b. In Section 2, there may be funding available for journal costs, if your department is not paying for figures, tables or photographs for your publication. Please state "YES" or "NO" in Section 2 of the form, if you need publication funding support.
- 2. Print your name, rank/grade, sign and date the form in the author's signature block or use an electronic signature.
- 3. Attach a copy of the 59 MDW IRB or IACUC approval letter for the research related study. If this is a technical publication/presentation, state the type (e.g. case report, QA/QI study, program evaluation study, informational report/briefing, etc.) in the "Protocol Title" box.
- 4. Attach a copy of your abstract, paper, poster and other supporting documentation.
- Save and forward, via email, the processing form and all supporting documentation to your unit commander, program director or immediate supervisor for review/approval.
- 6. On page 2, have either your unit commander, program director or immediate supervisor:
 - a. Print their name, rank/grade, title; sign and date the form in the approving authority's signature block or use an electronic signature.
- 7. Submit your completed form and all supporting documentation to the CRD for processing (59crdpubspres@us.af.mil). This should be accomplished no later than 30 days before final clearance is required to publish/present your materials. If you have any questions or concerns, please contact the 59 CRD/Publications and Presentations Section at 292-7141 for assistance.
- 8. The 59 CRD/Publications and Presentations Section will route the request form to clinical investigations, 502 ISG/JAC (Ethics Review) and Public Affairs (59 MDW/PA) for review and then forward you a final letter of approval or disapproval.
- Once your manuscript, poster or presentation has been approved for a one-time public release, you may proceed with your publication or presentation submission activities, as stated on this form. Note: For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.
- 10. If your manuscript is accepted for scientific publication, please contact the 59 CRD/Publications and Presentations Section at 292-7141. This information is reported to the 59 MDW/CC. All medical research or technical information publications/presentations must be reported to the Defense Technical Information Center (DITC). See 59 MDWI 41-108, Presentation and Publication of Medical and Technical Papers, for additional information.
- 11. The Joint Ethics Regulation (JER) DoD 5500.07-R, Standards of Conduct, provides standards of ethical conduct for all DoD personnel and their interactions with other non-DoD entities, organizations, societies, conferences, etc. Part of the Form 3039 review and approval process includes a legal ethics review to address any potential conflicts related to DoD personnel participating in non-DoD sponsored conferences, professional meetings, publication/presentation disclosures to domestic and foreign audiences, DoD personnel accepting non-DoD contributions, awards, honoraria, gifts, etc. The specific circumstances for your presentation will determine whether a legal review is necessary. If you (as the author) or your supervisor check "NO" in block 17 of the Form 3039, your research or technical documents will not be forwarded to the 502 ISG/JAC legal office for an ethics review. To assist you in making this decision about whether to request a legal review, the following examples are provided as a guideline:

For presentations before professional societies and like organizations, the 59 MDW Public Affairs Office (PAO) will provide the needed review to ensure proper disclaimers are included and the subject matter of the presentation does not create any cause for DoD concern.

If the sponsor of a conference or meeting is a DoD entity, an ethics review of your presentation is not required, since the DoD entity is responsible to obtain all approvals for the event.

If the sponsor of a conference or meeting is a non-DoD commercial entity or an entity seeking to do business with the government, then your presentation should have an ethics review.

If your travel is being paid for (in whole or in part) by a non-Federal entity (someone other than the government), a legal ethics review is needed. These requests for legal review should come through the 59 MDW Gifts and Grants Office to 502 ISG/JAC.

If you are receiving an honorarium or payment for speaking, a legal ethics review is required.

If you (as the author) or your supervisor check "YES" in block 17 of the Form 3039, your research or technical documents will be forwarded simultaneously to the 502 ISG/JAC legal office and PAO for review to help reduce turn-around time. If you have any questions regarding legal reviews, please contact the legal office at (210) 671-5795/3365, DSN 473.

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement:

"The views expressed are those of the [author(s)] [presenter(s)] and do not reflect the official views or policy of the Department of Defense or its Components"

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving humans:

"The voluntary, fully informed consent of the subjects used in this research was obtained as required by 32 CFR 219 and DODI 3216.02_AFI 40-402."

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving animals, as required by AFMAN

"The experiments reported herein were conducted according to the principles set forth in the National Institute of Health Publication No. 80-23, Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act of 1966, as amended."

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PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS								
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NEW FAQS BASED ON RESIDENT DIRECTOR'S FEEDBACK

1) I'm a resident and would like to begin a research project. Where do I start?

The 59 MDW has a Research Reference Guide that can be used to get started on the research protocol application process. It provides helpful information on research topic and hypothesis development, training requirements for investigators, funding options, and important points of contact. The reference guide is designed to help you avoid common research pitfalls during your residency.

It is recommended that you also contact the 59 MDW Office of the Chief Scientist (59 MDW/ST) at 210-292-2097 to see if there are any current studies that you could join. You may also access their webpage. You can also contact the 59 MDW Clinical Research Division (CRD) Office of Research Protocol Support at 210-292-2977 or 210-292-5203 and request a meeting (via telephone or inperson with them) to discuss your research idea.

2) How does a researcher prepare a proposal to go to the 59th MDW IRB?

This process is outlined in the 59 MDW Research Reference Guide. Assistance from 59 MDW/ST to prepare a proposal can be arranged by calling 210-292-2097. Once you know what type of research you would like to conduct, contact the 59 MDW Office of Research Protocol Support at 210-292-2977 or 210-292-5203 for help with application form and template selection. Alternatively, you may access these forms at the CRD Knowledge Exchange website HERE. Submit your completed application to the Office of Research Protocol Support as instructed. Submission deadlines can be found HERE.

3) I'm a resident/staff member. What support and help can the Clinical Research Division provide me for my research?

If you intend to conduct your research at the Clinical Research Division, we can provide you with protocol preparation, statistical, laboratory, pathology, surgical, and veterinary support as outlined <u>HERE</u>. If you have competed for Clinical Investigation Program (CIP) funding or are a resident and have received a CIP funding letter, we will assist you with obtaining your supplies and equipment. For more funding information, contact Dr. Anneke Bush at 210-292-7295.

The CRD facility primarily supports training, readiness, and graduate health sciences education. Staff researchers not funded through the Clinical Investigation Program will be charged to use CRD facility resources.

4) My sense is that the 59 MDW HRPP and Research Approval Process are more geared towards protecting the institution and research staff. Who protects the patient?

While it is important that the 59 MDW and its employees conduct business in accordance with federal, state, and local regulations and laws, the protection of human research participants and medical patients is of paramount importance. The 59 MDW commander has established the <u>Human Research Protection Program (HRPP)</u>, which is executed by the <u>HRPP Steering Committee</u>. This committee, composed of 59 MDW leadership, is charged with ensuring the protection of institutional research interests, developing research policy in accordance with federal and state regulations, and directly assisting the 59 MDW Institutional Review Board (IRB) – an independent research regulatory compliance board – in safeguarding the health and well-being of all research

subjects. In addition, the 59 MDW is actively seeking national accreditation from the Association for the Accreditation of Human Research Protection Programs (AAHRPP) — the organization that represents the benchmark for excellence in human research subject protection. Finally, all active research is subject to Post-Approval Monitoring (PAM) in order to ensure that research is being conducted as approved by the IRB. Post-Approval Monitors have received commander permission to visit researchers at their work and/or research sites to conduct audits of investigator study records and research procedures, and may observe participant consenting as required.

If you are concerned that the health and well-being of research participants are possibly being jeopardized, please contact one of the following immediately:

Dr. Rocky Calcote – Human Research Administrator 210-292-5203/DSN 554-5203 rocky.d.calcote.civ@mail.mil

Lt Col Della Howell – 59 MDW IRB Chair 210-916-7727 della.l.howell.mil@mail.mil

Dr. Earl Grant, Jr. – Director of Quality Assurance and Education/Post-Approval Monitor 210-292-5146/DSN 554-5143 earl.grant.civ@mail.mil

Dr. Debra Niemeyer – 59 MDW Authorized Institutional Official/59 MDW Chief Scientist 210-292-3355/DSN 554-3355 debra.m.niemeyer.civ@mail.mil

Maj Gen Bart Iddins – 59 MDW Institutional Official/59 MDW Commander 210-292-7351/DSN 554-7351 bart.o.iddins.mil@mail.mil

5) I'm a resident/staff member. Is research at the 59 MDW worth my time and effort?

This is an excellent question because it shows that you understand that research requires commitment and a lot of time. You are encouraged to speak-up and ask any questions you might have regarding conducting research at the 59 MDW. A good place to start would be with your residency mentor/advisor, your supervisor, and your peers/colleagues. They will be able to give you honest feedback on the research process and whether they believe you have the time and ability to complete a research project. We also encourage you to read the 59 MDW Research Reference Guide and contact the 59 MDW Office of Research Protocol Support at 210-292-2977 with any specific questions regarding your proposed research.

The USAF has a proud heritage of conducting innovative and cutting-edge research. Indeed, there have been <u>78 Nobel Laureates</u> in the last 60 years who have conducted research through the Air Force. You have an opportunity to become a part of this legacy. Your jumping-off point is to create a unique research question or idea to investigate, create your research design, and submit your research protocol application to the IRB to initiate the iterative review process. Approval of your research study is proof that your chain-of-command, and the institution as a whole, believes your research is worth your time and effort.

6) I am a resident/staff member. How can I obtain on-duty time to conduct my research? Like any professional work in the USAF, there are processes and protocols that must be followed to allow providers and researchers dedicated time with which to conduct research. We recommend that you talk with your supervisor for how they want your research time allocated and recorded. If your clinic includes research in their MEPRS code for you then time is already built into your assigned work unit already. If you are a resident, your program director will determine your time for involvement in research.

If your research involves a process improvement such as a knowledge product that supports patient care, ask if your clinic wants your research time recorded as a process improvement or contact the 59 MDW Resource Management Office (RMO) [Douglas Stevens – Director of Strategic Business Operations (59 MDW/SGARX); douglas.e.stevens8.civ@mail.mil; 210-292-8342] with questions on how to record research time. You may also enroll in the 59 MDW Gateway Academy to gain knowledge of all the process improvements being developed at the 59 MDW. Call the Gateway Innovation Center at 210-292-8303 or contact TSgt Vanessa Arthur at vanessa.n.arthur.mil@mail.mil for more information.

- 7) I am a staff member now, but when I was a resident at the 59 MDW, I alone was expected to be responsible for all aspects of my research. It has recently been observed that current resident investigators do not always advocate for their research and, instead, allow their research staff to make decisions for the study and dictate study requirements. Some investigators feel out-of-touch with their own studies. Do you have any advice?
 - It is federally-mandated (<u>DoDI 3216.02 AFI 40-402</u>, Enclosure 2, §11.a) that all Principal Investigators assume complete responsibility and accountability for the conduct of their research. We do not have an answer as to why residents do not sometimes speak-up and feel empowered in regard to their research. In the case of conflicting personalities or issues with research staff, it is recommended that the Investigator talk with their supervisor in order to identify a resolution for any problems that may exist within or between research teams. In the interest of safeguarding the health and well-being of their research subjects and protecting the integrity of their research study design, Investigators must address personality conflicts decisively and as soon as possible.
- 8) Can a 59 MDW Office of Research Protocol Support staff member come to my office to assist me with the completion of my protocol application documents?
 Unfortunately, no.

IRB members and staff members of the Office of Research Protocol Support cannot complete an investigator's application documents for them, nor are they resourced to travel to an investigator's work site. The exception is our Post-Approval Monitoring program that has been granted commander approval to visit investigator work/research sites. CRD staff, however, would be more than happy to answer any question you may have via email or on the phone. Also, the Office of the Chief Scientist may be able to provide research coordinators to directly assist investigators with completion of IRB forms and templates.

9) As a resident, I have a very hectic schedule. Is the CRD able to work around my schedule in terms of IRB review and approval for my research? Unfortunately, no.

The IRB has a specific schedule for receipt of IRB documents and for reviewing and preparing them for convened IRB review. The IRB meets on the 4th Tuesday of every month, except in December when it meets on the 2nd Wednesday. See below for the current IRB Meeting schedule.

IRB DATE	NEW PROTOCOL DEADLINE	PROGRESS REPORT/OTHER REPORT DEA		
22 Nov 2016	24 Oct 2016	If study expires 23 Nov–26 Dec, submit by:	11 Oct 2016	
NO Dec IRB		If study expires 27 Dec-24 Jan, submit by:	11 Oct 2016	
24 Jan 2017	28 Nov 2016	If study expires 25 Jan-28 Feb, submit by:	8 Nov 2016	
28 Feb 2017	23 Jan 2017	If study expires 29 Feb-28 Mar, submit by:	10 Jan 2017	
28 Mar 2017	27 Feb 2017	If study expires 29 Mar-25 Apr, submit by:	14 Feb 2017	
25 Apr 2017	27 Mar 2017	If study expires 26 Apr-23 May, submit by:	14 Mar 2017	
23 May 2017	24 Apr 2017	If study expires 24 May-27 Jun, submit by:	11 Apr 2017	
27 Jun 2017	22 May 2017	If study expires 28 Jun-25 Jul, submit by:	9 May 2017	
25 Jul 2017	26 Jun 2017	If study expires 26 Jul-22 Aug, submit by:	13 Jun 2017	
22 Aug 2017	24 Jul 2017	If study expires 23 Aug-26 Sep, submit by:	11 Jul 2017	
26 Sep 2017	28 Aug 2017	If study expires 27 Sep-24 Oct, submit by:	8 Aug 2017	
24 Oct 2017	25 Sep 2017	If study expires 25 Oct-28 Nov, submit by:	12 Sep 2017	
28 Nov 2017	23 Oct 2017	If study expires 29 Nov–13 Dec, submit by:	10 Oct 2017	
13 Dec 2017	13 Nov 2017	If study expires 14 Dec-23 Jan, submit by:	13 Nov 2017	
23 Jan 2018	25 Dec 2017	If study expires 24 Jan-27 Feb, submit by:	12 Dec 2017	
27 Feb 2018	22 Jan 2018	If study expires 28 Feb-27 Mar, submit by:	9 Jan 2018	
27 Mar 2018	26 Feb 2018	If study expires 28 Mar-24 Apr, submit by:	13 Feb 2018	
24 Apr 2018	26 Mar 2018	If study expires 25 Apr-22 May, submit by:	13 Mar 2018	
22 May 2018	23 Apr 2018	If study expires 23 May-26 Jun, submit by:	10 Apr 2018	
26 Jun 2018	28 May 2018	If study expires 27 Jun-24 Jul, submit by:	8 May 2018	
24 Jul 2018	25 Jun 2018	If study expires 25 Jul-28 Aug, submit by:	12 Jun 2018	
28 Aug 2018	23 Jul 2018	If study expires 29 Aug-25 Sep, submit by:	10 Jul 2018	
25 Sep 2018	27 Aug 2018	If study expires 26 Sep-23 Oct, submit by:	14 Aug 2018	
23 Oct 2018	24 Sep 2018	If study expires 24 Oct-27 Nov, submit by:	11 Sep 2018	
27 Nov 2018	22 Oct 2018	If study expires 28 Nov–12 Dec, submit by:	9 Oct 2018	
12 Dec 2018	12 Nov 2018	If study expires 13 Dec-22 Jan, submit by:	12 Nov 2018	

10) Is the CRD involved in the creation or maintenance of Cooperative Research and Development Agreements (CRADA)?

No. The AFMSA/ORTA office handles all CRADA-related matters. You may contact Ms. Sherrilynne Cherry at 210-292-2570 or sherrilynne.d.cherry.civ@mail.mil for more information.

11) I want to conduct research with an external non-DoD institution that already has an IRB-approved study. I would rely on this external institution's IRB as my IRB of Record. What do I need to do to gain approval to begin research with this group?

We would recommend that you first consult HRPP OI-028, Cooperative Off-Site Research.

Generally, if you are going to rely on an external protocol as an AF collaborator, and rely on their IRB determination, then the study must be vetted by the Air Force Medical Support Agency Surgeon General's Research Oversight and Compliance Division (AFMSA/SGE-C) through a Human Research Protection Official (HRPO) review and approval. The 59 MDW IRB would not be the IRB of Record

since we would defer regulatory oversight to the external non-DoD institution's IRB. You would not be able to begin the study at the 59 MDW until the SGE-C HRPO has approved the study. If you rely on the external protocol, then you would be required to use their research-related support documents (e.g., Protocol, Informed Consent Document, HIPAA Authorization, etc.). The SGE-C HRPO would determine if these documents can be used, as-written, for Active Duty personnel and DoD beneficiaries.